MAY 3 0 2002

K021374

EXHIBIT #1

510(K) SUMMARY

This summary of 5l0(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA l990 and 21 CFR §807.92.

The assigned 5l0(k) number is:_____

1. **Submitter's Identification:**

Toei Electric Co., Ltd.
771, Shimosakunobe, Takatsu-ku
Kawasaki-shi, Kanagawa-Ken 213-0033
Japan

Date Summary Prepared: April 29, 2002

Contact Person: Mr. Kazuhiro Tachibana
Overseas Sales Marketing Manager

3. **Name of the Device:**

Toesco Aqua Blue LED Light Curing Device

3. **Predicate Device Information:**

K# 002925, CoolBlu Curing Light, Dental System.com, Inc., Heathrow, Florida

4. **Device Description:**

The Toesco Aqua Blue Led Light Curing Device is a gun-handle shaped dental curing light that is intended to polymerize dental materials such as resins and sealants by transmitting light through a light guiding tip. The source of blue light is a light-emitting diode. The device has two optional curing modes: two full power modes and a 2-step curing mode. It incorporates three pre-set programs and seven user programs. The power source is a 7.4 V Lithium Ion Battery. Wavelength is 450 nm – 480 nm, with wavelength peaking at 470nm.

5. **Intended Use:**

The Toesco Aqua Blue LED Light Curing Device is intended to provide visible light irradiation for the curing of dental VLC resin products.

6. **Comparison to Predicate Devices:**

Both the subject and predicate devices use an LED light source, but of differing light intensities (subject device is 330mW/cm^2 and predicate device is 320mW/cm^2, and a battery power source (subject device uses lithium ion battery, 7.4V and predicate device uses Nickel Cadmium battery – power consumption for subject device is 23VA, and predicate device is 18VA). The respective configurations of the two devices show no major differences, and, are substantially equivalent in intended use and design.

7. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

IEC 60601-1-1, IEC 60601-1-2, Battery and Charger Testing, Environmental Testing, Reliability Testing.

8. **Discussion of Clinical Tests Performed:**

Not Applicable

9. **Conclusions:**

The Toesco Aqua Blue LED Light Curing Device has the same intended use and similar characteristics as the CoolBlu Curing Light Device. Moreover, non-clinical testing (bench testing) demonstrates that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, the Toesco Aqua Blue LED Light Curing Device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 3 0 2002

Toei Electric Company Limited
C/O Susan D. Goldstein-Falk
MDI Consultants, Incorporated
55 Northern Boulevard, Suite 200
Great Neck, New York 11021

Re: K021374
Trade/Device Name: Toesco Aqua Blue LED Light Curing Device
Regulation Number: 872.6070
Regulation Name: Ultraviolet Activator for Polymerization
Regulatory Class: II
Product Code: EBZ
Dated: April 29, 2002
Received: May 01, 2002

Dear Ms. Goldstein-Falk :

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Patricia Cucinotta for

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit B

510(k) Number (if known): K021374

Device Name: Toesco Aqua Blue LED Light Curing Device

Indications For Use:

The Toesco Aqua Blue LED Light Curing Device is intended to provide visible light irradiation for the curing of dental VLC resin products.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **(Per 21 CFR 801.109)** **OR** **Over-The-Counter Use** ____ **(Optional Format 1-2-96)**

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K021374